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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,031	10/23/2003	William F. Crismore	7404-571/BMID-9738RE-DIV2	5358

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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,031	CRISMORE ET AL.	
	Examiner	Art Unit	
	Lyle A. Alexander	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Reissue Applications

This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification, as described in USP 5,997,817, does not teach a "fill line" to determine the proper amount of sample. Rather, it appears the patent teaches an area where the user can see if the proper amount of sample is present.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the independent claims "at least working..." appears to be a typographical error. For the purposes of examination will assume – at least one working ...-- was intended.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 68-104 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 122-155 and 104-130 of copending Application No. 10/409,721 and 10/693,305 respectively.

Although the conflicting claims are not identical, they are not patentably distinct from

each other because all are directed to an indistinguishable invention of test strip comprising a capillary channel, electrodes, an edge to receive the sample and a reagent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 68-104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims13-14 of U.S. Patent No. 6,767,440. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an electrochemical glucose detector comprising electrodes, reagent and an edge to receive the sample.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 68-104 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Diebold et al.(USP 5,437,999).

Diebold et al. teach the same structure of a device with cut out portions, a vent and reagents associated with the electrodes.

Claims 68-104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al. (USP 5,942,102) or Hodges et al. (USP 6,174,420)

The Hodges et al. references teach an electrochemical test device for the determination of glucose in blood. Hodges ('102) teach a working electrode(2), a counter electrode(16) and a dried reagent of GOD and ferrocyanide. The device is

assembled between two layers and notched on opposite sides to admit the sample by capillary and allow air to escape out of the other side (see column 5 lines 3-10). The claimed *"atleast working and counter electrodes"* have been read on the taught **working electrode(2) and counter electrode(16).** The claimed *"test reagent"* has been read on **the taught dried reagent of GOD and ferrocyanide.** The claimed *"capillary channel and a vent in fluid communication with a sample application port ... the edge defining an indentation"* has been read on the taught **one notch side admits the sample by capillary action and air to escapes from the opposite notch (e.g. the opposite notch has been read on the vent).** Hodges('420) is applied in the identical manner.

Claims 68-104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Charlton et al. (USP 5,798,031).

Charlton et al. in figure 1 an electrochemical glucose sensor. **Electrodes(38 and 39)** have been read on the claimed *"atleast working and counter electrodes"*. The **reagent layer(40)** has been read on the claimed *"test reagent"*. The claimed *"capillary channel and a vent in fluid communication with the capillary channel ... with a sample application port"* has been read on the taught **concave space(48) that admits the sample to a capillary action and vent(50).**

Claims 68-104 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ikeda et al. (USP 5,575,895) or Yoshioka et al. (USP 5,264,103).

Ikeda et al. teach an electrochemical device for the determination of glucose in a blood sample. Insulating base plate(1) is provided with conductors(2,3), **working**

electrode(4) and counter electrode(5) that have been read on the claimed "*atleast working and counter electrodes*". Reaction **layer(7)** is in contact with the electrode system has been read on the claimed *"test reagent"*. Slotted spacer(8) provides a notch for sample acquisition and is in communication with channel(12) and vent(13) has been read on the claimed *"capillary channel and a vent in fluid communication with the capillary channel ... with a sample application port"* . Yoshioka et al. has been applied in the identical manner.

Claims 68-104 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by

Galen et al.

Galen et al. teach a test strip having a sample application port (20) along an edge having notch(19) that assures proper alignment in the detector. Column 10-12 teach a fructosamine multiplayer test device where the multiple layers all have the same notch cut out. Column 1 1 lines 30 + teach use of radiation blocking layers and contamination prevention layers which have been read on the claimed "substantially ' opaque podion" and the "transparent window" respectively.

Claims 68-104 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Seshimoto et al. (USP 4,684,445), Columbus (USP 4,473,457) or Ikeda et al. (USP 5,798,031).

These references all teach an electrochemical test device with a transparent and opaque portions, a conductive track, vents and a sample application port.

Response to Arguments

Applicant's arguments filed 4/19/07 have been fully considered but they are not persuasive.

In addition to Applicants' remarks Poto et al., Gin, Galen et al. and Nagase et al. fail to teach a device with electrodes and the Office has vacated the rejections over these references.

Applicants' state Charlton et al., Seshimoto et al., Columbus and Ikeda et al. all fail to teach the claimed "fill line". The Office does not believe Applicants' have support for such an amendment. Even if Applicants' could show support for "fill line", the Office would maintain it is notoriously well known in the analytical art to provide a fill line to let the user know if enough fluid sample has been added. All of these reference could be rejection under 35 USC 103 stating incorporation of a fill line it within the skill of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743